

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

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| VENTANA MEDICAL SYSTEMS, INC., |) | |
| |) | |
| Plaintiff, |) | |
| v. |) | C.A. No. 05-CV-10614-GAO |
| |) | |
| VISION BIOSYSTEMS INC., |) | |
| |) | |
| Defendant. |) | |
| _____ |) | |

**VISION BIOSYSTEMS INC.'S OPENING BRIEF IN SUPPORT OF ITS MOTION
FOR SUMMARY JUDGMENT OF NON-INFRINGEMENT**

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TABLE OF CONTENTS

| | Page |
|---|------|
| INTRODUCTION | 1 |
| SUMMARY OF ARGUMENT | 1 |
| STATEMENT OF FACTS | 3 |
| I. The Asserted Claims of the '861 Patent Require Automatically Determining Reagents by Reading a Slide "Bar Code." | 3 |
| II. During Prosecution of the '861 Patent, Ventana Surrendered Coverage of All Means Other Than "Bar Codes" for Automatically Determining Reagents. | 4 |
| A. December 1999: Ventana Submitted Broad Claim 72 Covering All Means of Automatic Determination and Narrower Claim 80 Limited to "Bar Codes." | 5 |
| B. May 2001: The PTO Rejected Claims 72 and 80 Based on the Stark, Sakurada and Saralegui References. | 6 |
| C. June 2001: Ventana Argued Against the Rejections and Argued That the Saralegui Reference, Which Disclosed Bar Codes, Was Not Prior Art. | 7 |
| D. August 13, 2001: The PTO Again Rejected Broad Claim 72 But Allowed Narrower Claim 80 Because Saralegui Was Not Prior Art. | 8 |
| E. August 28, 2001: Ventana Responded to the PTO's Rejection by Canceling Broad Claim 72, Accepting a Narrow Patent Limited to Slide "Bar Codes." | 8 |
| III. Vision Redesigned and Improved Upon its Previous Instrument to Create the "Bond-OCR," which Does Not Use Slide "Bar Codes." | 9 |
| IV. Ventana's Own Later Continuation Patent Applications Reveal Ventana's Admission That OCR Was Well-Known by 1990 and That Ventana Could Have Drafted Claims Broader Than the "Bar Code" Claims of the '861 Patent. | 10 |
| ARGUMENT | 11 |
| I. The "Bond-OCR" Does Not Literally Infringe the '861 Patent Claims. | 12 |
| II. Ventana is Barred by Prosecution History Estoppel from Asserting That the "Bond-OCR" Infringes the '861 Patent Claims Under the Doctrine of Equivalents. | 13 |
| A. Prosecution History Estoppel Applies Because Ventana Made a Narrowing Amendment During Prosecution. | 14 |
| B. Ventana Cannot Rebut the Festo Presumption of No Equivalents. | 15 |

TABLE OF CONTENTS

(continued)

| | Page |
|--|-------------|
| 1. Ventana Does Not (and Cannot) Argue That OCR Was Unforeseeable in 2001, When Ventana Amended its '861 Patent Claims. | 15 |
| 2. Ventana Cannot Show That the Rationale for its Amendment Was Merely “Tangential” to the Alleged Equivalent. | 16 |
| 3. Ventana Does Not (and Cannot) Argue That Some Other Reason Applies for Rebutting the Festo Presumption. | 19 |
| C. Ventana’s Narrowing Amendment in Rewriting Claim 80 (Now Claim 1) Also Presumptively Bars All Equivalents for the Substantively Same Limitation in Claim 88 (Now Claim 5). | 19 |
| CONCLUSION..... | 20 |

TABLE OF AUTHORITIES

| | Page |
|---|---------------------------|
| Cases | |
| <i>Bayer AG v. Elan Pharm. Research Corp.</i> , 212 F.3d 1241 (Fed. Cir. 2000)..... | 12 |
| <i>Biagro Western Sales, Inc. v. Grow More, Inc.</i> , 423 F.3d 1296 (Fed. Cir. 2005)..... | 12, 14, 18 |
| <i>Builders Concrete, Inc. v. Bremerton Concrete Prods. Co.</i> , 757 F.2d 255 (Fed. Cir. 1985)..... | 20 |
| <i>Cross Med. Prods., Inc. v. Medtronic Sofamor Danek, Inc.</i> , 480 F.3d 1335 (Fed. Cir. 2007)..... | 16 |
| <i>Deering Precision Instruments, L.L.C. v. Vector Distribution Sys., Inc.</i> , 347 F.3d 1314 (Fed. Cir. 2003)..... | 20 |
| <i>Desper Prods., Inc. v. QSound Labs, Inc.</i> , 157 F.3d 1325 (Fed. Cir. 1998)..... | 3, 20 |
| <i>Exhibit Supply Co. v. Ace Patents Corp.</i> , 315 U.S. 126 (1942)..... | 13 |
| <i>Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.</i> , 344 F.3d 1359 (Fed. Cir. 2003) (en banc) (“ <i>Festo IX</i> ”)..... | 1, 14, 15, 16, 19 |
| <i>Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.</i> , 535 U.S. 722 (2002) (“ <i>Festo VIII</i> ”) | 1, 13, 14, 15, 16, 18, 19 |
| <i>Glaxo Wellcome, Inc. v. Impax Labs., Inc.</i> , 356 F.3d 1348 (Fed. Cir. 2004)..... | 20 |
| <i>Honeywell Int’l Inc. v. Hamilton Sundstrand Corp.</i> , 370 F.3d 1131 (Fed. Cir. 2004)..... | 15 |
| <i>Modine Mfg. Co. v. United States Int’l Trade Comm’n</i> , 75 F.3d 1545 (Fed. Cir. 1996)..... | 20 |
| <i>Rhodia Chimie v. PPG Indus., Inc.</i> , 402 F.3d 1371 (Fed. Cir. 2005)..... | 17 |

INTRODUCTION

Defendant Vision BioSystems, Inc. (“Vision”) respectfully submits this opening brief in support of its motion for summary judgment of non-infringement of U.S. Patent No. 6,352,861 (“the ’861 patent”).

The issue presented in this motion—application of the doctrine of prosecution history estoppel under the *Festo* cases¹—is purely a matter of law, appropriately resolved on summary judgment. Resolution of this motion in Vision’s favor will effectively end the case, rendering trial unnecessary.

SUMMARY OF ARGUMENT

The scope of a patent is defined by its claims. Patent claims inform the public of what is covered by the patent, and, just as importantly, what is not. Indeed, uncertainty in the scope of a patent can stifle legitimate competition, a result the patent laws seek to avoid. Thus, the patent laws require patentees to draft their patent claims clearly and distinctly, to give the public notice as to what is, and what is not, within the scope of the patent.

During the prosecution of the application for the ’861 patent, plaintiff Ventana Medical Systems, Inc. (“Ventana”) originally submitted a claim that recited the broad step of “automatically determining” the reagents to dispense onto a slide. Such a claim arguably would have broadly covered any means of “automatically determining” the reagents to dispense onto a slide, whether through the use of bar codes or any other means. However, the U.S. Patent & Trademark Office (“PTO”) repeatedly rejected this broad claim. In order to get the patent application allowed by the PTO, Ventana surrendered this broad claim and pursued a narrower claim limited to automatically determining the reagents to dispense only by “reading a slide bar code.” Ventana thus gave the public notice that it was no longer claiming other means of “automatically determining” the reagents to dispense.

¹ *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722 (2002) (“*Festo VIII*”); *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 344 F.3d 1359 (Fed. Cir. 2003) (en banc) (“*Festo IX*”).

In this case, Ventana asserts that Vision's "Bond-OCR" instruments infringe the '861 patent. Previously, in September 2004, in C.A. No. 03-CV-10391-GAO, this Court ruled on summary judgment that Vision's prior "Bond-bar code" instruments, which used bar codes on slides, infringed the '861 patent. In response to that ruling, and even though Vision maintains that the '861 patent is invalid, Vision redesigned its Bond instruments. As a result of that redesign effort, Vision developed an innovative way of allowing continued operation of the instrument even when the instrument cannot identify a slide label. The redesigned Bond instruments print slide labels with alphanumeric slide identifiers that are interpreted by the instrument's computer using Optical Character Recognition ("OCR"). These "Bond-OCR" instruments do not print or read slide bar codes. In the "Bond-OCR," if the instrument cannot identify the label, the software displays an image of the label and allows an operator to identify the label by reading the label. This is possible only because Vision's OCR labels are readily human-readable, unlike bar codes. Vision's "Bond-OCR" thus has improved functionality not possible with slide bar codes.

Summary judgment of non-infringement is appropriate. The '861 patent requires reading a slide "bar code" to determine reagents to dispense. The "Bond-OCR" instruments do not read slide bar codes, so there is no literal infringement. In addition, Ventana cannot assert that the "Bond-OCR" instruments infringe under the doctrine of equivalents. Under the *Festo* cases, Ventana's cancellation of its broad claim in favor of its narrower claim with the "bar code" limitation gives rise to prosecution history estoppel which precludes Ventana from reclaiming other ways of automatically determining the reagents to dispense, such as by OCR. The *Festo* cases set forth three ways in which a patentee may attempt to rebut the estoppel, but, as a matter of law, Ventana cannot make the required showing for any of these three rebuttal criteria. Thus, prosecution history estoppel is fatal to Ventana's infringement claim.

STATEMENT OF FACTS

I. The Asserted Claims of the '861 Patent Require Automatically Determining Reagents by Reading a Slide “Bar Code.”

Ventana asserts claims 1, 2, 3, 5, 6 and 8 of the '861 patent against the “Bond-OCR” instruments. Claims 1 and 5 are independent claims. The other claims depend from either claim 1 or claim 5. Because a dependent claim is not infringed if the independent claim from which it depends is not infringed, it is only necessary to address claims 1 and 5 on this motion.²

As reflected in the language highlighted below, claims 1 and 5 both require the step of “reading [a] slide bar code” to indicate the reagents to be applied to the slide. In other words, the claims, by the literal language chosen by Ventana, cover only procedures that involve reading “bar codes” on slides.

Claim 1 reads as follows:

1. A method of dispensing reagents onto a slide, the method comprising the steps of:
 - providing at least one reagent container;
 - providing at least one slide on a slide support;
 - automatically identifying the reagent container using a computer;
 - automatically determining whether reagent in the reagent container should be dispensed onto the slide; and
 - dispensing the reagent in the reagent container onto the slide based on the determination of whether the reagent in the reagent container should be dispensed on the slide,
 - wherein the step of automatically determining whether reagent in the reagent container should be dispensed onto the slide includes the steps of:
 - providing a bar code reader;
 - reading a slide bar code placed on the slide using the bar code reader thereby acquiring slide information, the slide information indicating reagents to be applied to the slide;** and
 - sending the information to the computer.

(Ex. 1, '861 patent, 24:52-25:7 (emphasis added)).

² *Desper Prods., Inc. v. QSound Labs, Inc.*, 157 F.3d 1325, 1338 n. 5 (Fed. Cir. 1998) (dependent claims “necessarily must be narrower than the independent claims,” and “cannot be infringed” if the independent claims are not infringed).

Claim 5 reads as follows:

5. A method of dispensing reagents onto a slide, the method comprising the steps of:
 providing a plurality of reagent containers in a slide support, each of the reagent containers having a reagent bar code;
 providing at least one slide on a slide support, **the slide having a bar code**;
 providing a bar code reader;
 reading the bar codes on the reagent containers;
 determining reagents in the reagent containers based upon the reading of the bar codes on the reagent containers;
reading the slide bar code on the at least one slide;
determining a sequence of reagents to be applied on the at least one slide based upon the reading of the slide bar code on the slide; and
 dispensing the reagents in the reagent containers based upon the sequence of reagents to be applied.

(Ex. 1, '861 patent, 25:19-39 (emphasis added)).

II. During Prosecution of the '861 Patent, Ventana Surrendered Coverage of All Means Other Than “Bar Codes” for Automatically Determining Reagents.

“Prosecution history estoppel”—which prevents a patentee from asserting infringement under the doctrine of equivalents—arises when a patentee, during prosecution of the application to obtain the patent, originally claimed the subject matter alleged to infringe but then narrowed the claim in response to a rejection. This is precisely what Ventana did during the prosecution of the '861 patent.

The timeline on the following page summarizes the relevant events in the '861 patent prosecution. Each of these events is described in further detail following the timeline. In summary, Ventana originally submitted a broad claim—claim 72—covering any means for “automatically determining” the reagents to apply to a slide, and a narrower claim—claim 80—that was limited to one specific way of “automatically determining” the reagents to apply to a slide, *i.e.*, by “reading a slide bar code.” Although the PTO initially rejected both claims, the PTO later allowed the narrower claim. In order to get the PTO to issue the '861 patent, Ventana **canceled** the broad claim 72, accepting a patent limited to automatic determination by “reading a slide bar code.” Narrow claim 80 became claim 1 of the '861 patent.

| <u>Dec. 1999</u> | <u>May 2001</u> | <u>June 2001</u> | <u>Aug. 13, 2001</u> | <u>Aug. 28, 2001</u> |
|--|--|--|---|---|
| Ventana submitted claims 72 & 80. | PTO issued Office Action. | Ventana submitted arguments. | PTO issued Office Action. | Ventana submitted Amendment. |
| 72. (BROAD) all means of “automatically determining” reagents to apply | 72. REJECTED by combining Stark, Sakurada (code marks) and Saralegui (bar codes). | Ventana argues that Stark and Sakurada do not suggest “automatically determining.” | 72. REJECTED by again combining Stark and Sakurada (code marks). | 72. (BROAD) CANCELED BY VENTANA. |
| 80. (NARROW) “reading a slide bar code ” to automatically determine reagents to apply | 80. REJECTED by combining Stark, Sakurada (code marks) and Saralegui (bar codes). | Ventana argues that Saralegui (bar codes) is not prior art. | 80. ALLOWED. Saralegui (bar codes) not prior art. | 80. (NARROW) REWRITTEN INDEPENDENT “reading a slide bar code ” to automatically determine reagents to apply |

Each of the above events is described in detail below.

A. December 1999: Ventana Submitted Broad Claim 72 Covering All Means of Automatic Determination and Narrower Claim 80 Limited to “Bar Codes.”

The ’861 patent was issued from U.S. Patent Application 09/452,309 (“the ’309 application”), filed in December 1999. At the beginning of the prosecution of the ’309 application, Ventana canceled original claims 1 through 71—which were the original claims from 1990 that were pursued in an earlier application to which the ’309 application claimed priority—and added new claims 72 through 113. (Ex. 2, Preliminary Amendment).

The prosecution events relating to claims 72 and 80 are pertinent to this motion. Claim 72 was a broad independent claim covering any means for “automatically determining” the reagents to dispense onto a slide. Claim 80 was a narrower dependent claim, which depended from claim 72 and therefore included all of the limitations of claim 72 as well as the additional limitations set forth in claim 80. The additional limitations of claim 80 recited one specific way for “automatically determining” the reagents to dispense onto a slide, *i.e.*, by “reading a slide bar code.”

Independent claim 72 was originally submitted as follows:

72. A method of dispensing reagents onto a slide, the method comprising the steps of:
providing at least one reagent container;
providing at least one slide on a slide support;
automatically identifying the reagent container using a computer;
automatically determining whether reagent in the reagent container should be dispensed onto the slide; and
dispensing the reagent in the reagent container onto the slide based on the determination of whether the reagent in the reagent container should be dispensed on the slide.

Dependent claim 80 was originally submitted as follows:

80. The method of claim 72 wherein the step of automatically determining whether reagent in the reagent container should be dispensed onto the slide includes the steps of:
providing a bar code reader;
reading a slide bar code placed on the slide using the bar code reader thereby acquiring slide information, the slide information indicating reagents to be applied to the slide; and
sending the information to the computer.

(Ex. 2 at 2-4 (emphasis added)).

B. May 2001: The PTO Rejected Claims 72 and 80 Based on the Stark, Sakurada and Saralegui References.

During prosecution, the PTO Examiner initially rejected claims 72 and 80 as unpatentable under 35 U.S.C. §103 as being an obvious combination of the Stark reference (Ex. 8) with the Sakurada reference (Ex. 9) and the Saralegui reference (Ex. 10). (Ex. 3, 5/10/01 Office Action, p. 4). The Examiner pointed out that Stark discloses an automated slide staining apparatus, but that Stark does not disclose detecting positions of slide samples or reagent containers, or a bar code reader for identifying types of reagents. (Ex. 3 at 5). However, the Examiner pointed out that Sakurada discloses reagents that are detected and identified by sensors, which read “code marks” on the reagent containers. These “code marks” are not bar codes. The Examiner cited to Figure 3 of Sakurada, as well as to text from column 4 of Sakurada, which reads as follows:

[T] o each reagent vessel 7 ... is attached a label 33 as shown in FIG. 3. The label 33 is provided thereon with **code marks** corresponding to the kinds of reagents contained in the reagent vessel 7 and to analysis item, for example, "**GOT**". The detector 31 functions to photoelectrically read out these **code marks**.

(Ex. 3 at 5; Ex. 9, Sakurada, col. 4, lines 3-9 (emphasis added) and Fig. 3).

Sakurada does not disclose bar codes, but the Examiner pointed out that Saralegui does, stating that Saralegui discloses "sample containers comprising bar code labels for identifying the appropriate process for the sample." (Ex. 3 at 5). Saralegui indeed discloses "bar code indicia label 42." (Ex. 10, Saralegui, 4:13). Accordingly, the Examiner rejected both claim 72 and claim 80 as obvious. (Ex. 3, at 4-5).

C. June 2001: Ventana Argued Against the Rejections and Argued That the Saralegui Reference, Which Disclosed Bar Codes, Was Not Prior Art.

In response to the Examiner's May 2001 rejections, Ventana submitted arguments. Ventana argued that Stark and Sakurada did not meet the limitations in claim 72 requiring "automatically identifying" the reagent containers and "automatically determining" whether reagent in the reagent containers should be dispensed onto a slide:

Stark does not teach or even suggest **automatically determining** whether reagent in the reagent container should be dispensed onto the slide. Rather, Stark only teaches that the slides must be **manually** inserted in the proper positions Sakurada does not disclose, or even suggest, **automatically determining**, based at least in part on information from the slide, whether reagent in the reagent container should be dispensed onto the slide.

(Ex. 5, 6/26/01 Amendment, pp. 10-11 (emphasis added)).

With respect to Saralegui, which the Examiner had relied on to show "bar codes" for the proposed combination with the Stark instrument, Ventana argued that the reference was not early enough to qualify as prior art. Ventana said:

The Saralegui reference has a filing date of January 25, 1993. As discussed above, the current invention claims a filing date of March 2, 1990. Therefore, the Saralegui reference is not prior art to the present invention.

(Ex. 5 at 11).

D. August 13, 2001: The PTO Again Rejected Broad Claim 72 But Allowed Narrower Claim 80 Because Saralegui Was Not Prior Art.

The Examiner did not accept Ventana's arguments regarding Stark and Sakurada. The Examiner did, however, accept Ventana's arguments that Saralegui was not early enough to constitute prior art. In the next Office Action, the Examiner again rejected claim 72 based on Stark and Sakurada, but not on Saralegui. (Ex. 6, 8/13/01 Office Action, pp. 2-3). Claim 72 required only "automatically determining" the reagents to apply, which could be accomplished by "code marks" as in Sakurada, so the Examiner did not need the "bar codes" of Saralegui to reject claim 72. However, claim 80 did require "bar codes." Thus, because the Examiner could no longer use Saralegui's "bar codes" as prior art, the Examiner withdrew the rejection of claim 80. (Ex. 6 at 6). The Examiner stated that claim 80, unlike claim 72, recited allowable subject matter, saying:

The following is a statement of reasons for the indication of allowable subject matter: . . . While numerous slide staining apparatus and methods exist, none of the prior art teaches or suggest providing a plurality of reagent containers in reagent support wherein each of the reagent container have a reagent **barcode**. The apparatus also providing slides on a slide support, each of the slides having at least one slide **bar code**. Wherein the apparatus provides a barcode reader for reading the **bar codes** on the reagent containers, determining reagents in the reagent containers based on the reading of the **bar codes**. Thereafter, the barcode reader reading the slide **bar codes** and determining the sequence of reagent to be applied on the slides base upon the reading of the slide **bar codes**.

(Ex. 6 at 6 (emphasis added)).

E. August 28, 2001: Ventana Responded to the PTO's Rejection by Canceling Broad Claim 72, Accepting a Narrow Patent Limited to Slide "Bar Codes."

If Ventana believed that it was entitled to claim means of "automatically determining" reagents other than by slide "bar codes," Ventana could have continued to argue against the rejection of claim 72. Alternatively, it could have amended its claims to expressly include means of identification other than bar codes. However, Ventana did not do this. Instead, Ventana **canceled** its broad claim 72. Ventana then rewrote dependent claim 80 into independent form, by adding all of the limitations of claim 72 into claim 80. (Ex. 7, 8/28/01 Amendment, pp. 1-3).

Thus, Ventana acquiesced to the Examiner's rejection of claim 72, and accepted the narrower claim 80 requiring slide "bar codes" in order to obtain allowance of the patent.

The '309 application was subsequently allowed and issued as the '861 patent. Claim 80 of the application became claim 1 of the '861 patent, asserted in this litigation. Accordingly, claim 1 of the '861 patent remains expressly limited to the use of slide "bar codes" for identifying the reagents to apply. Claim 5 of the '861 patent, the only other asserted independent claim, is similarly limited to the use of slide "bar codes" for identifying the reagents to apply.

III. Vision Redesigned and Improved Upon its Previous Instrument to Create the "Bond-OCR," which Does Not Use Slide "Bar Codes."

There can be no question that Vision independently designed its Bond instruments, which are significantly different in many respects from the device disclosed in the '861 patent. As just one example, the hardware is completely different. The device shown in the '861 patent has a carousel of reagents rotating over a carousel of slides, resembling a birthday cake. (Ex. 1 at Fig. 3). By contrast, Vision's Bond instrument has a processing module into which three individual rectangular slide trays may be loaded. (Barrow Decl., ¶¶ 4-5). This provides the advantage of allowing trays of slides to be loaded while other trays are in progress. (*Id.* at Ex. A, p. 23).

In C.A. No. 03-CV-10391-GAO, this Court ruled on summary judgment that the '861 patent claims were broad enough to encompass Vision's prior "Bond-bar code" instruments, which used bar codes on slides. (D.I. 103). Although Vision maintains that it has a strong invalidity defense to the '861 patent, to avoid any further dispute, Vision removed slide bar codes from the Bond instruments. In doing so, Vision developed an innovative way of allowing the instrument to continue to operate even when it cannot automatically identify a slide label.

A slide for the redesigned Bond instrument is shown below. As can be seen, the slide labels use a string of human and machine readable letters and numbers, *e.g.*, "OOFL OU6." Once the slides are loaded into the processing module and the operator starts the run, an imager in the processing module takes a picture of each slide label and sends the picture to the computer.

The computer then automatically recognizes the alphanumeric identifier from the image using optical character recognition (“OCR”). (Barrow Decl., ¶¶ 3-5).

The beauty of the “Bond-OCR” is that it provides an advantage that cannot be realized using bar codes. If the computer is unable to automatically identify a slide—such as if the label is skewed or obscured—the slide can still be identified manually by the operator of the machine. Thus, when the “Bond-OCR” system is unable to automatically identify a slide, the system software displays an image of the label on the computer screen. The operator can then read the displayed image and manually identify the slide to the computer. If the label carried only a bar code, the operator would not be able to read the label, since bar codes, unlike OCR characters, are not readily readable by humans. Thus, unlike a bar code instrument, the “Bond-OCR” provides operators with the ability to continue a staining run even if the instrument cannot automatically recognize a slide label. (Barrow Decl., ¶¶ 4-6).



IV. Ventana’s Own Later Continuation Patent Applications Reveal Ventana’s Admission That OCR Was Well-Known by 1990 and That Ventana Could Have Drafted Claims Broader Than the “Bar Code” Claims of the ’861 Patent.

When Ventana canceled the broad claim 72 (and other claims) in the ’861 patent prosecution, Ventana said it was doing so “without prejudice in order to prosecute these claims in a continuation application.” (Ex. 7, p. 2). Ventana has indeed continued to pursue the broader claim coverage in continuation applications, thus far without success. Ventana’s continuation applications are revealing. They contain Ventana’s admission that OCR was well-known in the field by 1990 and demonstrate that, when Ventana narrowed its claims to “bar codes” in the ’861 patent in 2001, Ventana certainly could have drafted a claim broad enough to cover OCR, if it believed it was entitled to such a claim.

Ventana filed continuation application 10/054,535 (“the ’535 application”) on January 22, 2002, with a new claim 72 similar to the old claim 72 that was rejected in the ’861 prosecution. (Ex. 11, pp. 2-3). As before, new claim 72 in the ’535 application recited

“automatically determining” the reagents to dispense. Ventana also submitted dependent claim 73 reciting automatically determining the reagents by “identifying information from the slide,” and dependent claim 75 requiring a slide “barcode.” (*Id.*). The PTO Examiner repeatedly rejected claims 72 and 73, but eventually allowed claim 75. (Ex. 12, p. 2; Ex. 13, p. 3; Ex. 14, p. 2 (rejecting claims 72 & 73) and p. 4 (allowing claim 75)). As in the ’861 patent, Ventana again accepted the narrower claim requiring a slide “barcode,” and the ’535 application matured into U.S. Patent No. 6,943,029. (Ex. 17; *see* claim 1, line 64 (“barcode”)). The only difference between rejected claim 73 and the claim ultimately allowed was one word—“barcode.” (*See* Ex. 15, comparing rejected claim 73 to issued claim 1).

Ever persistent, on November 17, 2004, Ventana filed yet another continuation application, 10/991,050 (“the ’050 application”). This time, Ventana filed a version of claim 72 that recited the step of automatically determining the reagents by reading an “optically-coded identifier” on the slide. (Ex. 16, p. 4). Ventana concurrently submitted a proposed amendment to its specification to refer to prior U.S. Patent 5,235,167, a patent that described both “bar codes” and “optical character recognition.” (Ex. 16 at 2; Ex. 18, col. 15, lines 52-61). Ventana said that the reference to U.S. Patent 5,235,167 was “to reflect the state of the art of barcodes and equivalent identifiers as of the earliest claimed filing date of the present application,” i.e., as of 1990. (Ex. 16 at 10).

Thus, Ventana is attempting to change its pending applications to include, for the first time, optical character recognition. In doing so, it has admitted that OCR was known as of 1990. This means that Ventana has no excuse for failing to include a claim directed to OCR in the ’861 patent, or in now asserting that “bar code” patent against Vision’s “Bond-OCR” device.

ARGUMENT

Infringement can be found in two different ways: literally and under the doctrine of equivalents. Literal infringement exists only where the accused product or method literally meets every limitation of a patent claim. *Bayer AG v. Elan Pharm. Research Corp.*, 212 F.3d

1241, 1247 (Fed. Cir. 2000). If an accused product or method does not literally infringe, it may nevertheless infringe under the doctrine of equivalents if it contains an equivalent of each limitation not met literally. *Id.* at 1251-1252. However, as explained below, infringement under the doctrine of equivalents can be found only if “prosecution history estoppel” does not apply.

I. The “Bond-OCR” Does Not Literally Infringe the ’861 Patent Claims.

A patent infringement determination proceeds in two steps. First, the claims are construed to determine their scope. Second, the properly construed claims are compared to the accused device or method. *Biagro Western Sales, Inc. v. Grow More, Inc.*, 423 F.3d 1296, 1301 (Fed. Cir. 2005). Claim construction is a question of law for the court. *Id.*

This Court has previously construed the “bar code” language of the ’861 patent claims. This Court found that “[a] bar code is commonly understood to be ‘a series of contiguous lines of like height coded by width and applied to an item for identification by an optical scanner, as for registering the price of a product.’” (D.I. 103 in 03-CV-10391, p. 8, *quoting Random House Webster’s College Dictionary* 110 (1992)). The Court cited a reference defining a “bar code” as using “a pattern of lines or bars.” (*Id.*, *citing The Columbia Encyclopedia* 238 (6th ed. 2000)). Ventana itself had advocated this construction, submitting evidence that a bar code is “a series of varying width vertical lines (called bars) and [intervening] spaces.” (D.I. 67 in 03-CV-10391, Showalter Decl., Ex. A, p. 1; *see also* Showalter Decl., ¶ 9). The Court held that, “properly construed, claim 1 discloses an invention in which a ‘bar code reader’ ‘read[s] a slide bar code,’ which is commonly understood to be a linear bar code” (D.I. 103 in 03-CV-10391, at 11).

The “Bond-OCR” slide labels do not have bar codes. They have labels using letters and numbers, which are interpreted by optical character recognition. Both claim 1 and claim 5 of the ’861 patent require “reading [a] slide bar code,” which the “Bond-OCR” does not do. Therefore, there can be no legitimate dispute that the use of the “Bond-OCR” instrument does not literally infringe the asserted claims. Summary judgment of no literal infringement is appropriate.

II. Ventana is Barred by Prosecution History Estoppel from Asserting That the “Bond-OCR” Infringes the ’861 Patent Claims Under the Doctrine of Equivalents.

The doctrine of equivalents allows a patentee to claim infringement by accused devices and methods that, although not meeting a claim limitation literally, nevertheless incorporate an equivalent to that limitation. Ventana asserts infringement under the doctrine of equivalents, alleging that the “Bond-OCR” performs the equivalent of “reading [a] slide bar code” by reading OCR labels. Vision disputes equivalence as a factual matter, but, even before reaching that fact question, Ventana’s argument fails as a matter of law. This is because Ventana’s abandonment of the broad claim scope during prosecution and its acquiescence to the narrow “bar code” claim scope gives rise to “prosecution history estoppel,” preventing Ventana as a matter of law from asserting infringement under the doctrine of equivalents:

Prosecution history estoppel requires that the claims of a patent be interpreted in light of the proceedings in the PTO during the application process. ... **[When a] patentee originally claimed the subject matter alleged to infringe but then narrowed the claim in response to a rejection, he may not argue that the surrendered territory comprised unforeseen subject matter that should be deemed equivalent to the literal claims of the issued patent.** On the contrary, “[b]y the amendment [the patentee] recognized and emphasized the difference between the two phrases[,] ... and [t]he difference which [the patentee] thus disclaimed must be regarded as material.”

Festo VIII, 535 U.S. at 733-734 (emphasis added), quoting *Exhibit Supply Co. v. Ace Patents Corp.*, 315 U.S. 126, 136-137 (1942).

In the landmark *Festo VIII* decision, the Supreme Court held that a narrowing amendment made to secure a patent gives rise to prosecution history estoppel. *Festo VIII* at 736. “A patentee’s decision to narrow his claims through amendment may be presumed to be a general disclaimer of the territory between the original claim and the amended claim.” *Id.* at 740. In other words, the narrowing amendment triggers a presumption that the amended limitations cannot be broadened beyond their literal words by resort to the doctrine of equivalents—infringement under the doctrine of equivalents simply will not apply. *Id.*

A patentee can rebut the presumption of prosecution history estoppel only by showing that “at the time of the amendment one skilled in the art could not reasonably be expected to have drafted a claim that would have literally encompassed the alleged equivalent.” *Id.* at 740-41. The Supreme Court set forth three ways in which a patentee can make such a showing: (1) where the equivalent was not foreseeable at the time of the amendment; (2) where the rationale underlying the amendment “bear[s] no more than a tangential relation” to the equivalent; or (3) where there is “some other reason” suggesting that the applicant could not have reasonably been expected to have drafted a claim to encompass the alleged equivalent. *Id.*

Prosecution history estoppel, including whether the patentee can rebut the *Festo* presumption of no equivalents, is a question of law for the Court. *Festo IX*, 344 F.3d at 1367-69. Summary judgment of non-infringement under the doctrine of equivalents is appropriate if prosecution history estoppel bars infringement by equivalents. *Biagro*, 423 F.3d at 1305-1307.

A. Prosecution History Estoppel Applies Because Ventana Made a Narrowing Amendment During Prosecution.

During prosecution of the application for the '861 patent, Ventana surrendered claim scope to get the patent. Ventana was pursuing claim 72 which broadly recited the step of “automatically determining” the reagents to apply to a slide. This claim, if valid, arguably would have covered any means for automatically determining the reagents for a slide, such as by a slide labeled with bar codes, “code marks” as in Sakurada, or OCR labels. However, the PTO repeatedly rejected claim 72. Rather than continue to pursue claim 72, Ventana canceled it. In its place, Ventana rewrote the narrower dependent claim 80—which required “reading a slide bar code”—into independent form, by incorporating all limitations of rejected claim 72. In doing so, Ventana limited the patented claims specifically to methods that automatically determine the reagents by “reading a slide bar code,” thereby excluding all other means of automatic identification. Claim 80 became claim 1 of the '861 patent.

Ventana’s cancellation of independent claim 72 in favor of dependent claim 80 was a narrowing amendment that surrendered all equivalents to the limitations of claim 80, *i.e.*, all

equivalents to “reading a slide bar code.” *Honeywell Int’l Inc. v. Hamilton Sundstrand Corp.*, 370 F.3d 1131, 1142-1144 (Fed. Cir. 2004) (“all equivalents” are surrendered “if, by canceling the original independent claim and rewriting the dependent claim[s] into independent form, the scope of subject matter claimed in the independent claim has been narrowed to secure the patent.”). Having surrendered all means of automatic determination other than slide bar codes, a presumption arises that bars Ventana from resort to the doctrine of equivalents.

B. Ventana Cannot Rebut the *Festo* Presumption of No Equivalents.

In order to recapture the surrendered territory—which Ventana would need to do to read its claims on the accused “Bond-OCR” instrument—Ventana must rebut the presumption of estoppel. That is, Ventana “**must** show that at the time of the amendment one skilled in the art could not reasonably be expected to have drafted a claim that would have literally encompassed the alleged equivalent,” using one of the three criteria set forth in *Festo VIII*. *Festo VIII*, 535 U.S. at 740-741 (emphasis added). As discussed below, Ventana cannot meet this burden.

1. Ventana Does Not (and Cannot) Argue That OCR Was Unforeseeable in 2001, When Ventana Amended its ’861 Patent Claims.

The *Festo* foreseeability rebuttal criterion asks whether the alleged equivalent would have been unforeseeable “at the time of the amendment.” *Festo IX*, 344 F.3d at 1369. An alleged equivalent that was known in the prior art was not unforeseeable. *Id.* At the time of Ventana’s narrowing amendment, *i.e.*, in August 2001, OCR was well-known. In Ventana’s ’050 application, Ventana admitted as much, submitting earlier U.S. Patent 5,235,167, a patent describing both “bar codes” and “optical character recognition,” and stating that it reflected “the state of the art” as of the filing date, *i.e.*, 1990. (Ex. 16 at 2, 10; Ex. 18, col. 15, lines 52-61).

As reflected in Ventana’s interrogatory response stating its infringement contentions, Ventana does not contend that OCR was unforeseeable. (Ex. 19, pp. 2-4, Resp. to Int. 14). Accordingly, the inapplicability of the “foreseeability” rebuttal criterion is not in dispute.

2. Ventana Cannot Show That the Rationale for its Amendment Was Merely “Tangential” to the Alleged Equivalent.

The *Festo* “tangential” rebuttal criterion applies where the rationale underlying the amendment bore no more than a “tangential” relation to the alleged equivalent. *Festo IX*, 344 F.3d at 1369. The inquiry under the “tangential” criterion “focuses on the objectively apparent reason for the narrowing amendment” which “should be discernible from the prosecution history record, if the public notice function of a patent and its prosecution history is to have significance.” *Id.* “[W]hether the patentee has established a merely tangential reason for a narrowing amendment is for the court to determine.” *Id.* at 1370.

In *Cross Med. Prods., Inc. v. Medtronic Sofamor Danek, Inc.*, 480 F.3d 1335 (Fed. Cir. 2007), the Federal Circuit made clear that “the tangential relation criterion for overcoming the *Festo* presumption is **very narrow**.” *Id.* at 1342. “[O]nly two cases have successfully invoked the tangential rebuttal principle in [the Federal Circuit],” and, as Judge Rader pointed out, even in those two cases the court “might well have justifiably reached a different conclusion in both.” *Id.* at 1346-1347 (Rader, J., concurring).

In *Cross Medical*, Medtronic “deliberately sought to design around the patented technology—a response that patent law encourages.” *Id.* at 1347. Medtronic “undoubtedly consulted the patent and adjusted its technology with reference to the claim language and prosecution history of the patent.” *Id.* Judge Rader pointed out that the “tangential” criterion must not “defeat principles of notice and proper procedures for designing around patented technology.” *Id.*; see also *Festo VIII*, 535 U.S. at 731 (“[The public] should be encouraged to pursue innovations, creations, and new ideas beyond the inventor’s exclusive rights.”).

Given the importance of the public notice function of the prosecution history, in order to prevail Ventana must prove that it is clear from the prosecution history itself that the rationale for the amendment was “tangential” to the subject matter that it is now trying to recapture. However, the prosecution history shows just the opposite. The PTO rejected claim 72 in light of the combination of Stark and Sakurada. Sakurada had “code marks” on the reagent containers,

not bar codes. Thus, the PTO stated it would allow claim 80, limited to bar codes, to issue in spite of Sakurada. In response, Ventana canceled the broad claim 72 that would have covered such “code marks” and instead pursued claim 80, limited to “bar codes.” The “bar code” limitation provided another way to distinguish the claim from Sakurada. By definition, then, the rationale for the amendment is not “tangential” to Ventana’s present attempt to broaden the “bar code” limitation to cover other types of codes. *See Rhodia Chimie v. PPG Indus., Inc.*, 402 F.3d 1371, 1383 (Fed. Cir. 2005) (the rationale for an amendment is not “tangential” if the amendment and the alleged equivalent both relate to the same parameter that was at issue during prosecution).

Despite these facts, Ventana attempts to rely on the narrow “tangential” criterion to save its infringement case. Ventana asserts that the rationale it advocated in the prosecution history was that the invention “automatically identifies reagent and protocols without operator input,” while the prior art required “an operator to identify the reagents and protocols and to place the slides in their correct, pre-assigned locations.” (Ex. 19 at 4). These arguments, however, were the unsuccessful arguments Ventana made in the prosecution with respect to claim 72, not claim 80. (Ex. 5 at 10-11). At the same time, Ventana **also** argued that Saralegui—which the Examiner was relying on to show “bar codes”—was not prior art. (Ex. 5 at 11). In response to these arguments, the Examiner **repeated** the rejection of claim 72 based on Stark and Sakurada, but **withdrew** the rejection of claim 80, thereby indicating that Ventana’s **successful** argument was that Saralegui and its bar codes were not prior art. (Ex. 6 at 2-3, 6). The Examiner explicitly allowed claim 80 because it required, *inter alia*, “at least one slide bar code” and determining reagents “based on the reading of the bar codes.” (Ex. 6 at 6). In response, and without substantive comment, Ventana canceled claim 72 and accepted “bar code” claim 80. (Ex. 7 at 1-3). The Examiner’s explicit “bar code” rationale for allowing claim 80 shows the rationale was not tangential; Ventana’s silence when accepting claim 80 is fatal to its contrary assertion. *Cf. Festo IX*, 344 F.3d at 1371-1372 (if the prosecution “reveals no reason” for the amendment, the patentee cannot show that it was tangential). Given this prosecution history,

Ventana cannot now simply argue that it did not really “need” to limit its claims to slide bar codes (as opposed to other types of slide codes) to obtain its patent. *See Biagro*, 423 F.3d at 1306 (rejecting patentee’s argument that “about 30 percent to about 40 percent” was tangential to equivalents above the 40 percent upper limit because only the 30 percent lower limit was needed to distinguish the art).

Further, it is important not to lose sight of the forest for the trees. The basic requirement of *Festo VIII* is that, to overcome the presumption of surrender, the patentee “*must* show that at the time of the amendment one skilled in the art could not reasonably be expected to have drafted a claim that would have literally encompassed the alleged equivalent.” *Festo VIII*, 535 U.S. at 741 (emphasis added). Overwhelming evidence demonstrates that Ventana cannot make this required showing—Ventana absolutely could have pursued a claim not limited to slide bar codes.

The prosecution record of the ’861 patent contains examples of codes other than bar codes. The Sakurada reference disclosed “code marks.” Another reference cited by Ventana broadly disclosed “optically readable code,” encompassing both bar codes and OCR. (Ex. 4, p. 3 (citing U.S. Pat. 5,646,046); Ex. 20, 6:10 (“**optically readable code**, such as a bar code **or other coding**, present on or incorporated into the sample collection tube or holding device”) (emphasis added)). These disclosures were directly in front of Ventana during prosecution, yet Ventana chose to narrow its claims to “bar codes” and exclude these other types of codes.

Ventana’s own statements during prosecution of the ’861 patent reveal that Ventana was well aware of codes other than bar codes. In addressing the Rokugawa reference, Ventana argued that Rokugawa does not teach bar coding “**or any other form** of ... automatic determination.” (Ex. 5 at 14). Ventana was thus demonstrably conscious of forms of automatic determination other than bar coding. Nevertheless, Ventana limited its claims to “bar codes.”

In Ventana’s ’050 continuation application, Ventana itself argued that OCR was part of “the state of the art” in the field of its invention in 1990, well before the 2001 amendment. Ventana cannot on the one hand assert that OCR was part of “the state of the art” in 1990 and on the other hand assert that it could not have been reasonably expected to draft a claim broad

enough to cover it in 2001. In the '050 application, Ventana submitted claims reciting an “optically-coded identifier.”³ Just as in that '050 application, Ventana could have submitted this language during prosecution of the '861 patent, instead of narrowing the claims to “bar codes.”

Given all of this, if Ventana believed it was entitled to a claim broad enough to cover OCR, Ventana could have and should have written such a claim while it was prosecuting the application for the '861 patent. Ventana simply cannot make the showing, required by *Festo VIII*, that “at the time of the amendment one skilled in the art could not reasonably be expected to have drafted a claim that would have literally encompassed the alleged equivalent.” *Festo VIII*, 535 U.S. at 741. Accordingly, Ventana cannot overcome the presumption that it surrendered coverage of subject matter other than bar codes. *Id.*

3. Ventana Does Not (and Cannot) Argue That Some Other Reason Applies for Rebutting the *Festo* Presumption.

The third *Festo* rebuttal criterion is also “narrow” and applies only where there is “some other reason” suggesting that the applicant could not reasonably have been expected to draft a broader claim. *Festo IX*, 344 F.3d at 1370. Ventana does not, because it cannot, dispute the inapplicability of this third *Festo* rebuttal criterion. (Ex. 19 at 2-4).

C. Ventana’s Narrowing Amendment in Rewriting Claim 80 (Now Claim 1) Also Presumptively Bars All Equivalents for the Substantively Same Limitation in Claim 88 (Now Claim 5).

Ventana’s cancellation of claim 72 in favor of narrower claim 80, now claim 1 of the '861 patent, also bars equivalents for asserted claim 5 of the '861 patent because claim 5 requires “reading the slide bar code on the at least one slide; determining a sequence of reagents to be applied on the at least one slide based upon the reading of the slide bar code on the slide,” which is substantively the same as the narrowing amendment of claim 1. When prosecution history estoppel applies to a limitation in one claim, it also applies to the same limitation in another claim, regardless of whether the second claim was amended during prosecution. *Deering*

³ Only time will tell whether Ventana can convince the PTO that it is entitled to these claims.

Precision Instruments, L.L.C. v. Vector Distribution Sys., Inc., 347 F.3d 1314, 1326 (Fed. Cir. 2003) (prosecution history estoppel applies to the same limitation in another claim “regardless of whether the claim was, or was not, amended during prosecution.” (citing *Builders Concrete, Inc. v. Bremerton Concrete Prods. Co.*, 757 F.2d 255, 260 (Fed. Cir. 1985)); see also *Glaxo Wellcome, Inc. v. Impax Labs., Inc.*, 356 F.3d 1348, 1356 (Fed. Cir. 2004) (“infectious estoppel”). Prosecution history estoppel applies to limitations that are substantively the same, even if they do not use identical language. *Modine Mfg. Co. v. United States Int’l Trade Comm’n*, 75 F.3d 1545, 1551 (Fed. Cir. 1996) (prosecution history estoppel applies to similar limitations “despite a difference in the words used”).

Accordingly, because estoppel applies to claim 1, it also applies to claim 5. Because all other asserted claims depend from either claim 1 or 5, summary judgment of non-infringement is appropriate. *Desper*, 157 F.3d at 1338 n. 5 (dependent claims “cannot be infringed” if the independent claims are not infringed).

CONCLUSION

For the reasons set forth above, Vision respectfully requests entry of summary judgment of non-infringement.⁴

Respectfully submitted,

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⁴ Resolution of this motion in Vision’s favor will end this case. The companion case of 03-CV-10391 would technically still be alive. However, Vision sold only a handful of the “Bond-barcode” instruments at issue in that case, and they have long since been discontinued. Accordingly, once the “Bond-OCR” is ruled not to infringe on summary judgment, the parties would likely resolve any remaining issues in 03-CV-10391.